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Conformity assessment — Requirements for bodies performing inspection

Évaluation de la conformité — Exigences pour les organismes effectuant des inspections

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives or www.iec.ch/members_experts/refdocs).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html. In the IEC, see www.iec.ch/understanding-standards.

This document was prepared by the ISO Committee on Conformity Assessment (CASCO), in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 1, *Criteria for conformity assessment bodies,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO/IEC 17020:2012), which has been technically revised.

The main changes are as follows:

— the categorization of the inspection body’s independence type has been changed to type A and type non-A;

— a definition of “item” and a definition of “client” have been included;

— a new subclause on the control of data and information and actions to address risks and opportunities has been added;

— the common elements in CASCO standards have been incorporated;

— the risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;

— there is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html and www.iec.ch/national-committees.

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Introduction

This document was developed to promote confidence in bodies performing inspection.

Inspection bodies perform inspection activities on behalf of private clients, their parent organizations, regulatory authorities, or others, with the objective of providing information about the conformity of inspected items with regulations, standards, specifications, inspection schemes or contracts. Inspection parameters include matters of quantity, quality, safety, fitness for purpose, and conformity of inspected item(s) with specified requirements (e.g. safety compliance of installations or systems in operation). This document provides requirements for the competence, impartiality and consistent operation of inspection bodies as a basis to promote confidence about and acceptance of inspection results by clients, regulatory authorities and others.

This document covers the activities of inspection bodies whose work can include the examination of materials, products, installations, plants, processes, work procedures or services, and the determination of their conformity with requirements and the subsequent reporting of results of these activities to clients and, when required, to regulatory authorities. Inspection can concern all stages during the lifetime of these items, including the design stage. Such work normally requires the exercise of professional judgement in performing inspection, in particular when assessing conformity with general requirements.

This document can be used as a requirements document for accreditation or peer-assessment or other assessments.

The requirements of this document can be interpreted when applied to particular sectors.

Inspection can be an activity embedded in a larger process. For example, inspection can be specified as a surveillance activity in a product certification scheme. Likewise, results of other conformity assessment activities can be used as an input when performing inspection activities. Inspection can be an activity that precedes maintenance or simply provides information about the inspected item with no determination of conformity with requirements.

The categorization of inspection bodies as type A and type non-A reflects the level of their independence. The impartiality requirements are equally applicable to both type A and type non-A inspection bodies.

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Conformity assessment — Requirements for bodies performing inspection

1 Scope

This document contains requirements for the competence and impartiality of bodies performing inspection, and for the consistent operation of their inspection activities.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000:2020, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
inspection
examination of an *item* (3.8) and determination of its conformity with detailed requirements or, on the basis of professional judgement, with general requirements

Note 1 to entry: Examination can include direct or indirect observations, which can include measurements or the output of instruments.

Note 2 to entry: Inspection results normally include a statement of conformity regarding the item. However, schemes or contracts can specify inspection as examination only.

[SOURCE: ISO/IEC 17000:2020, 6.3, modified — In the definition, "object of conformity assessment" has been replaced by "item"; the original Notes 2 and 3 to entry have been removed; a new Note 2 to entry has been added.]

3.2
inspection body
body that performs *inspection* (3.1)

3.3
inspection scheme
inspection programme
set of rules and procedures that describes the *item* (3.8), identifies the specified requirements and provides the methodology for performing *inspection* (3.1)

Note 1 to entry: Inspection schemes can be operated at the international, regional, national, sub-national or industry sector level.

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Note 2 to entry: A scheme that includes inspection can provide methodology for activities in either all or only in some of the conformity assessment functions (see ISO/IEC 17000:2020, Annex A). It can include methodology for inspection only (a determination function activity) or for other determination function activities. The scheme can include methodology for selection function activities and, in addition, it can include methodology for review, decision, attestation function activities

Note 3 to entry: The inspection scheme can specify independence requirements.

[SOURCE: ISO/IEC 17000:2020, 4.9, modified — In the preferred term and the admitted term, "conformity assessment" has been replaced by "inspection"; in the definition, "objects of conformity assessment" has been replaced by "item"; "conformity assessment" has been replaced by "inspection"; the original three Notes to entry have been replaced by three new ones.]

3.4
impartiality
objectivity with regard to the outcome of an *inspection* (3.1)

Note 1 to entry: Objectivity means that conflicts of interest do not exist or are resolved so as not to adversely influence activities of the *inspection body* (3.2).

Note 2 to entry: Other terms that are useful in conveying the element of impartiality are: freedom from conflict of interests, freedom from bias, lack of prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment, balance.

[SOURCE: ISO/IEC 17000:2020, 5.3, modified — In the definition, "conformity assessment activity" has been replaced by "inspection"; Note 1 to entry has been changed and Note 2 to entry has been added.]

3.5
appeal
request by the *client* (3.7) to an *inspection body* (3.2) for reconsideration by that body of a decision it has made relating to the conformity of the *item* (3.8) inspected

Note 1 to entry: An appeal is only possible if a statement of conformity has been issued.

[SOURCE: ISO/IEC 17000:2020, 8.6, modified — In the definition, "person or organization that provides, or that is, the object of conformity assessment to a conformity assessment body or an accreditation body" has been replaced by "client to an inspection body"; "that object" has been replaced by "the conformity of the item inspected"; Note 1 to entry has been added.]

3.6
complaint
expression of dissatisfaction, other than *appeal* (3.5), by any person or organization to an *inspection body* (3.2), relating to the activities of that body, where a response is expected

[SOURCE: ISO/IEC 17000:2020, 8.7, modified — In the definition, "a conformity assessment body or an accreditation body" has been replaced by "an inspection body".]

3.7
client
person or organization requesting *inspection* (3.1) of an *item* (3.8)

Note 1 to entry: The client can be different from the provider of the item.

3.8
item
object of *inspection* (3.1) to which the specified requirements for the inspection apply

Note 1 to entry: The term “item” is used in this document to encompass product, process, service, material, location, facility, premises, installation, or parts of thereof, or their design, as appropriate.

Note 2 to entry: The object of inspection can be a group of objects or a single object.

Note 3 to entry: An item can be inspected at any stages, e.g. design stage, type examination, initial inspection, in-service inspection or under surveillance.

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Note 4 to entry: Inspection of processes can include personnel, facilities, technology or methodology.

4 General requirements

4.1 Impartiality

4.1.1 Inspection activities shall be undertaken impartially.

4.1.2 The inspection body shall be responsible for the impartiality of its inspection activities and shall not allow commercial, financial or other pressures to compromise its impartiality.

4.1.3 The inspection body shall monitor its activities and its relationships to identify threats to its impartiality on an ongoing basis. This monitoring shall include the relationships of its personnel.

NOTE A relationship can be based on ownership, governance, management, personnel, shared resources, finances, contracts or marketing (including branding and sponsoring) and the payment of sales commissions or other inducements for the referral of new clients. Such relationships do not necessarily present a body with a threat to impartiality.

4.1.4 If a threat to impartiality is identified, its effect shall be eliminated or minimized so that the impartiality is not compromised. The inspection body shall demonstrate how it eliminates or minimizes such threats.

4.1.5 The inspection body shall have top management commitment to impartiality.

4.1.6 The inspection body shall be structured and managed so as to safeguard impartiality.

4.1.7 All personnel of the inspection body, either internal or external, that could influence the inspection activities shall act impartially. In particular, personnel involved in inspection activities shall not be remunerated in a way that influences the results of inspections.

4.2 Confidentiality

4.2.1 The inspection body shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of inspection activities. The inspection body shall inform the client, in advance, of the information it intends to place in the public domain. Except for information that the client makes publicly available, or when agreed between the inspection body and the client, all other information is considered proprietary information and shall be regarded as confidential.

NOTE Legally enforceable commitments can be, for example, contractual arrangements or commitments related to confidentiality policy published on the inspection body’s website or in the inspection body’s documentation.

4.2.2 When the inspection body is required by law or authorized by contractual arrangements to release confidential information, the client concerned shall be notified of the information released, unless prohibited by law.

4.2.3 Information about the client obtained from sources other than the client (e.g. complainant, regulatory authorities) shall be treated as confidential, unless agreed by the source.

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or persons acting on the inspection body's behalf, shall keep confidential all information obtained or created during the performance of the body's inspection activities.

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5 Structural requirements

5.1 Independence

The inspection body shall meet independence requirements specified in Annex A, based on the conditions under which it performs its inspection activities and, if applicable, as required by the inspection scheme.

NOTE An inspection body can meet different independence requirements (i.e. type A, type non-A) for different inspection activities.

5.2 Legal entity and liabilities

5.2.1 The inspection body shall be a legal entity, or a defined part of a legal entity. The legal entity is legally responsible for the inspection body and all its inspection activities.

NOTE A governmental inspection body is a legal entity on the basis of its governmental status.

5.2.2 An inspection body that is part of a legal entity shall be identifiable within that entity.

NOTE Identifiable means visible in the general organization and structure of the legal entity.

5.2.3 The inspection body shall define and document the inspection activities for which it conforms to the requirements of this document.

NOTE The description of the activities includes defining the general field and range of inspection (e.g. categories or sub-categories of products, processes, services, or installations) and the stage of inspection, and, where applicable, the regulations, inspection scheme, standards or specifications containing the requirements against which the inspection will be performed.

5.2.4 The inspection body shall have adequate provisions (e.g. insurance or reserves) to cover liabilities arising from its activities. The inspection body shall:

a) analyse the risks arising from the inspection activities;

b) assess the potential liabilities associated with identified risks;

c) assure that the level of provisions established is consistent with those liabilities.

NOTE The liability can be assumed by the state in accordance with national laws, or by the organization of which the inspection body forms a part.

5.2.5 The inspection body shall have documentation describing the contractual conditions under which it provides the inspection, except when it provides inspection services to the legal entity of which it is a part. In this case, internal agreements shall be established.

NOTE The contractual conditions cover the general and specific conditions for the performance of the inspections.

5.3 Organization and management

5.3.1 The inspection body shall:

a) define its organization and management structure, its place within any parent organization and the relationship between management, technical activities and support services;

b) specify the responsibility, authority and interrelationships of all personnel who manage or perform work affecting the results of its inspection activities;

c) maintain its capability to perform inspection activities as described in 5.2.3;

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d) document its procedures to the extent necessary to ensure the consistent application of its inspection activities and the validity of the results.

NOTE An inspection body can perform simulated inspections to maintain the capability for inspection activities performed infrequently.

5.3.2 The inspection body shall have technical management who has overall authority and responsibility for the:

a) development of inspection activities including inspection methods and associated processes;

b) performance of monitoring (see 6.1.5);

c) access to the necessary resources;

d) determination of requirements for competence of personnel;

e) provision of technical aspects of contractual arrangements;

f) performance of inspection activities.

5.3.3 The inspection body technical management shall be technically competent for the operation of an inspection body.

5.3.4 The inspection body shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to perform their duties, including:

a) implementation, maintenance and improvement of the management system;

b) identification of deviations from the management system;

c) initiation of actions to prevent or minimize such deviations;

d) reporting to inspection body's management on the performance of the management system and any need for improvement;

e) ensuring the effectiveness of the inspection body’s activities.

5.3.5 The inspection body shall document the duties, responsibilities and authorities for each function involved in its inspection activities in a job description or other documentation.

NOTE The functions involved in inspection activities are inspectors and other positions which can have an effect on the management, performance, recording or reporting of inspections.

6 Resource requirements

6.1 Personnel

6.1.1 The inspection body shall have access to a sufficient number of competent persons to perform the type, range and volume of its inspection activities. The inspection body shall ensure that each person clearly understands their duties, responsibilities, and authorities within the scope of the functions they perform.

6.1.2 The inspection body shall have a documented process for managing competence of its personnel involved in inspection activities. The process shall address the following:

a) determination of the competence requirements including, where needed, for making professional judgement (e.g. education, training, technical knowledge, skills or experience);

b) selection of personnel;

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c) initial training of personnel;

d) authorization of personnel;

e) monitoring of competence of personnel;

f) continual training.

6.1.3 The personnel performing the inspection shall have knowledge, to the extent required, for the type of inspection undertaken, of the following:

a) the technology used for the manufacture of the products inspected, the operation of processes and the delivery of services;

b) the way in which products are used, processes are operated, and services are delivered;

c) any defects which can occur during the use of the product, any failures in the operation of the process and any deficiencies in the delivery of services;

d) the significance of deviations in the normal use of products, the operation of processes and the delivery of services.

6.1.4 The initial training shall include an induction period and a mentored working period with authorized and competent personnel for the relevant inspection activity.

6.1.5 Personnel involved in inspection activities shall be monitored at a defined frequency by authorized and competent personnel in accordance with a monitoring programme.

NOTE The following can be considered in the design of the monitoring programme:

— the risks and complexities of the inspections;

— results of previous monitoring activities;

— technical, procedural or legislative developments relevant to the inspections;

— inspection activities which use new technology.

6.1.6 Results of monitoring shall be used as a means of identifying training needs (see 6.1.8) and shall be considered for maintenance of authorisation.

NOTE Monitoring can include a combination of techniques, such as on-site observations, report reviews, interviews, simulated inspections and other techniques to assess performance, and depends on the nature of the inspection activities.

6.1.7 Each inspector shall be observed performing inspection, unless there is sufficient supporting evidence that the inspector is continuing to perform competently.

NOTE 1 Depending on the fields, types and ranges of inspection covered by the inspector's authorizations, there can be more than one observation per inspector necessary to adequately cover the whole range of required competencies. Also, more frequent observations can be necessary if there is a lack of evidence of continuous competent performance.

NOTE 2 Sufficient evidence of an inspector's continuous competent performance can be substantiated by a combination of information such as satisfactory:

— performance of examinations and determinations;

— outcome of monitoring;

— outcome of separate evaluations to confirm the outcome of the inspections;

— outcome of mentoring and training;

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— results of examination by a competent body, e.g. a body operating certification of persons.

6.1.8 The inspection body shall identify training needs and provide relevant training to personnel involved in the inspection activities to keep pace with technology developments, inspection methods and other relevant changes depending on their competence, experience and upon the results of monitoring (see 6.1.7).

6.1.9 The inspection body shall have documented information demonstrating competence of its personnel (see 6.1.2).

6.2 Facilities and equipment

6.2.1 The inspection body shall have available, suitable and adequate facilities and equipment to ensure that inspection activities and all associated activities are performed in a competent and safe manner.

NOTE The inspection body is not necessarily the owner of the facilities or equipment that it uses. Facilities and equipment can be borrowed, rented, hired, leased or provided by another party (e.g. the manufacturer or installer of the equipment). However, the responsibility for the suitability and the calibration status of the equipment used in the inspection activities, whether owned by the inspection body or not, lies solely with the inspection body.

6.2.2 The inspection body shall have rules for the access to, and the use of, specified facilities and equipment used to perform inspections.

6.2.3 The inspection body shall ensure the continued suitability of the facilities and of the equipment mentioned in 6.2.1 for their intended use.

NOTE Continued suitability can be established by visual inspection, functional checks, periodic maintenance or recalibration.

6.2.4 All equipment having a significant influence on the results of the inspection shall be determined, and, where appropriate:

a) be uniquely identified;

b) be subjected to in-service checks according to a procedure, when necessary, to maintain confidence in the performance of the equipment;

c) for measuring equipment, be calibrated before being put into service, and thereafter calibrated according to an established programme.

NOTE 1 Inspection bodies can document and retain the rationale for decisions on the significance of influence of equipment on the inspection, including environmental conditions, when relevant.

NOTE 2 The procedure in b) can specify the nature of such checks, the frequency and acceptance criteria.

6.2.5 The inspection body shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in 6.2.4 to ensure proper functioning and to prevent contamination or deterioration.

6.2.6 The inspection body shall verify that equipment conforms to specified requirements before being placed into service or returned to service.

6.2.7 The inspection body shall ensure that when measurement results have a significant influence on the result of the inspection, or when so required by the inspection scheme, the measurement results are metrologically traceable to the International System of Units (SI) through at least one of the following:

a) calibration provided by a competent laboratory;

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NOTE 1 Laboratories fulfilling the requirements of ISO/IEC 17025 are considered to be competent.

b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI;

NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

c) direct realization of the SI units ensured by comparison, directly or indirectly, with national standards or international standards.

NOTE 3 Details of practical realization of the definitions of some important units are given in Reference [3].

NOTE 4 ISO/IEC 17025:2017, Annex A provides additional information on metrological traceability.

6.2.8 When metrological traceability to the SI units is not technically possible, the metrological traceability to an appropriate reference shall be ensured by, for example:

a) certified values of certified reference materials provided by a competent producer;

NOTE Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

6.2.9 If the inspection body uses technology, in connection with inspections (e.g. computers or automated equipment, data processing, artificial intelligence, augmented reality or remote inspection techniques), it shall ensure that:

a) the technology is suitable and adequate for use;

NOTE This can be done by the following:

— validation of calculations before use;

— periodic revalidation of related hardware and software;

— revalidation whenever changes are made to related hardware or software;

— software updates implemented as required.

b) procedures are established and implemented for protecting the integrity and security of data;

c) equipment, including hardware and software, is maintained to ensure proper functioning.

6.2.10 The inspection body shall have documented procedures for dealing with defective equipment. Defective equipment shall be removed from service by segregation and clearly identified as defective by prominent labelling or marking. The inspection body shall examine the effect of defects on previous inspections and follow the procedure in 8.5.

6.2.11 Relevant information on the equipment, including software, shall be recorded. This shall include identification and, where appropriate, information on calibration and maintenance.

6.3 Externally provided products and services

6.3.1 The inspection body shall ensure that only suitable externally provided products and services that affect inspection activities are used, when such products and services:

a) are intended for incorporation into its own inspection activities;

b) are provided, in part or in full, directly to the client by the inspection body, as received from the external provider;

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c) are used to support the operation of the inspection body.

NOTE Products can include, for example, equipment, installations, consumable materials and reference materials. Services can include, for example, calibration services, testing services in the framework of inspection process, inspection services, facility and equipment maintenance services, IT services, expertise services and auditing services.

6.3.2 The inspection body shall have a procedure and retain records for:

a) defining, reviewing and approving the inspection body's requirements for externally provided products and services;

b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;

c) ensuring that externally provided products and services conform to the inspection body's established requirements, or when applicable, to the relevant requirements of this document or of other relevant standards for conformity assessment bodies, before they are used;

d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

6.3.3 The inspection body shall itself normally perform the inspections that it contracts to undertake. The use of externally provided inspection activities for part of the inspection or the entire inspection shall be used in exceptional circumstances.

NOTE 1 Examples of exceptional circumstances can be:

a) an unforeseen or abnormal overload;

b) key inspection personnel being temporarily unavailable;

c) key facilities or equipment being temporarily unfit for use.

NOTE 2 The terms "subcontracting", "outsourcing" and "externally provided inspection activities" are considered to be synonyms.

NOTE 3 Where the inspection body engages individuals to provide additional resources or competence, these individuals are not considered to be external service providers, as long as they operate under the inspection body's management system (see 6.1).

NOTE 4 The use of external service providers for activities referred to in 6.3.1, such as testing, calibration or IT services, is not restricted to exceptional circumstances, provided that the requirements of 6.3.1 and 6.3.2 are fulfilled.

6.3.4 The inspection body shall inform the client of its intention to use externally provided inspection activities for part of the inspection, or the entire inspection, to provide the client with an opportunity to object in advance.

6.3.5 Whenever externally provided inspection activities form part of an inspection or the entire inspection, the responsibility for the inspection results and any determination of conformity of the item inspected with the requirements shall remain with the inspection body.

6.3.6 The inspection body shall retain documented information for approved external service providers and for which services the approval applies.

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7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1 The inspection body shall have a procedure for the review of inspection requests, tenders and contracts. The procedure shall ensure that:

a) the inspection to be performed is defined, the item to be inspected is clearly identified and the requirements to be fulfilled are adequately specified, documented and understood;

NOTE 1 The requirements can be part of the inspection scheme.

b) the inspection body has the capability, including adequate resources, to meet the client requirements;

c) the appropriate inspection methods are available or are to be developed to meet the client requirements;

d) the requirements, including any special conditions of the client, are adequately specified and understood, so that clear instructions can be issued to personnel performing the required inspection activities;

e) the requirements of the request, tender, contract or work order have been met.

NOTE 2 For routine or repeated work requests, reviews of requests, tenders and contracts can be performed in a simplified way.

7.1.2 The inspection body shall inform the client if a requested inspection is considered to be inappropriate.

7.1.3 Any differences between the request or tender and the contract shall be resolved before inspection activities start.

7.1.4 Each contract shall be acceptable to both the inspection body and the client. Deviations requested by the client shall not impact the validity of the results.

7.1.5 Records of review of requests, tenders and contracts, including any significant changes, shall be retained.

7.2 Inspection methods and procedures

7.2.1 The inspection body shall perform inspections using appropriate methods and procedures.

NOTE The requirements against which the inspection is performed are normally specified in regulations, standards, specifications, inspection schemes or contracts. Specifications can include client or in-house requirements.

7.2.2 Where inspection methods and procedures are not defined, the inspection body shall develop specific methods and procedures to be used (see 7.2.3).

7.2.3 The inspection body shall use standard inspection methods or procedures. In cases where non-standard inspection methods or procedures are used, they shall be appropriate and documented.

NOTE A standard inspection method or procedure is one that has been published, for example, in international, regional or national standards, or by reputable technical organizations or associations or by co-operation of several inspection bodies or in relevant scientific literature or journals. This implies that methods or procedures developed by any other means, including by the inspection body itself or by the client, are considered to be non-standard methods or procedures. Modifications of standard methods or procedures are also considered to be non-standard methods or procedures.

7.2.4 Development and modification of inspection methods or procedures shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources.

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7.2.5 The inspection methods or procedures shall address:

a) the inspection techniques to be used and, where appropriate, the measurements to be taken, including adequate information on the equipment and facilities to be used;

NOTE An inspection scheme can include the methodology to evaluate the uncertainty of the measurement processes.

b) activities for which the inspector's judgement may rely on the use of technology;

c) inspection planning and sampling, where the absence of such instructions can jeopardize the effectiveness of the inspection process;

d) when sampling is relevant to the validity of the outcome of inspection activities, the inspection body shall establish a sampling plan and method; where appropriate, sampling plans should be based on statistical methods; additionally, records of sampling shall be maintained, including details such as the method used, date and time, personnel involved, and any deviations from the plan, to ensure traceability;

e) information supplied by any other party (including the client) as part of the inspection process, and how the integrity and the validity of such information shall be verified to the extent appropriate for the intended use of this information;

f) inspection results from artificial intelligence or digital developments;

g) the use of safety equipment and the rules or instructions for performing inspections in a safe manner;

h) where applicable, the criteria to make the decision on conformity of the inspection item;

i) which particular equipment has a significant influence (if any) on the result of the inspection and when relevant, under which conditions (such as environmental).

7.2.6 The inspection body shall validate non-standard inspection methods or procedures including when technology is used. The validation shall be appropriate to meet the needs of the given application or field of application. Records of the validation shall be retained.

NOTE 1 Technology can be, for instance, but not limited to, digital developments, modelling, the use of artificial intelligence or remote techniques.

NOTE 2 The techniques used for method validation can be one of, or a combination of, the following:

a) systematic assessment of the factors influencing the result;

b) testing method robustness through variation of controlled parameters, such as inspector, equipment, etc.;

c) comparison of results achieved with other validated methods

7.3 Handling of items

7.3.1 The inspection body shall ensure that items to be inspected are uniquely identified in order to avoid confusion regarding the identity of such items.

7.3.2 The inspection body shall establish whether the item to be inspected is in a ready state for the intended inspection activities, where applicable. Where there is any doubt as to the item's suitability for the inspection to be performed, or where the item does not conform to the description provided, this shall be recorded and the inspection body shall contact the client before proceeding.

7.3.3 The inspection body shall have documented procedures and appropriate facilities to avoid deterioration or damage to the item while under its responsibility.

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7.4 Inspection records

7.4.1 Observations or data obtained in the course of inspections shall be recorded in a timely manner so as to prevent loss of relevant information. Calculations and data transfers shall be checked in an appropriate and systematic manner.

NOTE Data can include textual material, digital data and anything else that is transferred from one (physical or digital) location to another where errors can be introduced.

7.4.2 The inspection body shall maintain records to demonstrate the effective fulfilment of the inspection procedures and to enable an evaluation of the inspection process.

7.4.3 The records shall identify equipment having a significant influence on the result of the inspection, the date of use, for each inspection activity, and when relevant, the conditions (such as environmental) under which the equipment was used.

7.4.4 The inspection body shall ensure that amendments to inspection records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date.

7.5 Control of data and information

7.5.1 The inspection body's system used for the collection, processing, recording, reporting, storage or retrieval of data relevant to inspection activities shall be validated. Whenever there are any changes, including inspection body software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.

NOTE Commercial off-the-shelf software in general use within its designed application range can be considered sufficiently validated.

7.5.2 Technical data and inspection records shall:

a) be safeguarded against unauthorized access, tampering and loss;

b) be maintained in a manner that ensures the integrity and security of the data and information; and

c) include information on system failures and the appropriate immediate and corrective actions.

7.6 Inspection report or inspection certificate

7.6.1 The work performed by the inspection body shall be covered by an inspection report or inspection certificate.

7.6.2 Any inspection report or certificate shall include, at least, the following:

a) identification of the issuing body;

b) unique identification of the inspection report;

c) date of issue;

d) date(s) of inspection;

e) identification of the item(s) inspected;

f) signature or other indication of approval, by authorized personnel;

g) a statement of conformity, where applicable;

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h) the inspection results, except in inspection certificates where they are available upon request and traceable to the report;

i) facility name or location of inspection when relevant.

NOTE 1 The inspection certificate is typically issued when there is a statement of conformity, which is accompanied by an inspection report.

NOTE 2 Examples of optional elements that can be included in inspection reports or certificates are listed in Annex B.

7.6.3 All information listed in 7.6.2 shall be reported correctly, accurately and clearly. Where the inspection report or inspection certificate contains results delivered by external providers, these results shall be clearly identified.

7.6.4 The inspection report or inspection certificate shall be traceable to the inspector(s) who performed the inspection.

7.6.5 Corrections, additions or amendments to an inspection report or inspection certificate after issue shall be recorded in accordance with the relevant requirements of this subclause (7.6). An amended report or certificate shall be issued and shall clearly identify the report or certificate replaced.

7.6.6 When agreed with the client, the results can be reported in a simplified way. Any information listed in 7.6.2 that is not reported to the client shall be readily available.

NOTE Reporting continues to meet applicable scheme requirements, regulatory and contractual obligations.

7.7 Handling of appeals

7.7.1 The inspection body shall have a documented procedure for handling appeals that shall include at least the following:

a) a description of the process for receiving and investigating the appeal, and deciding what actions shall be taken in response;

b) tracking and recording the appeals, including actions undertaken to resolve it;

c) ensuring appropriate action is taken.

7.7.2 A description of the handling process for appeals shall be publicly available.

7.7.3 The inspection body shall acknowledge receipt of the appeal, and provide the appellant with the outcome and, if applicable, progress reports.

7.7.4 The inspection body receiving the appeal shall be responsible for gathering all necessary information to determine whether the appeal is valid.

7.7.5 The inspection body shall be responsible for all decisions for the process for handling appeals.

7.7.6 The decision on the appeal shall be made by, or reviewed and approved by, persons not involved in the decision that is the subject of the appeal in question.

7.7.7 Investigation and decision on appeals shall not result in any discriminatory actions.

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7.8 Handling of complaints

7.8.1 The inspection body shall have a documented procedure for handling complaints that shall include at least the following:

a) a description of the process for receiving, substantiating and investigating the complaint, and deciding what actions shall be taken in response;

b) tracking and recording the complaint, including the actions undertaken to resolve it;

c) ensuring appropriate action is taken.

7.8.2 A description of the process for handling complaints shall be publicly available.

7.8.3 Upon receipt of a complaint, the inspection body shall confirm whether the complaint relates to its inspection activities and, if so, shall resolve the complaint.

7.8.4 The inspection body receiving the complaint shall be responsible for gathering all necessary information to determine whether the complaint is substantiated.

7.8.5 Whenever possible, the inspection body shall acknowledge receipt of the complaint, and provide the complainant with the outcome and, if applicable, progress reports.

7.8.6 Investigation and resolution of complaints shall not result in any discriminatory actions.

7.8.7 The resolution of complaints shall be made by, or reviewed and approved by, persons not involved in the subject of the complaint in question. Where resources do not permit this, any alternative approach shall not compromise impartiality.

8 Management system requirements

8.1 General

8.1.1 The inspection body shall establish, document, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of this document.

8.1.2 The management system of the inspection body shall include at least the following:

— policies and responsibilities (8.2);

— documented information (8.3);

— actions to address risks and opportunities (8.4);

— corrective actions (8.5);

— internal audits (8.6);

— management review (8.7).

8.1.3 An inspection body may meet 8.1.2 by establishing, implementing and maintaining a quality management system (e.g. in accordance with the requirements of ISO 9001). This quality management system shall support and demonstrate the consistent fulfilment of the requirements of this document.

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8.2 Policies and responsibilities

8.2.1 The inspection body's top management shall establish, document, and maintain policies and objectives for fulfilment of the requirements of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the inspection body's organization.

8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the inspection body.

8.2.3 The inspection body's top management shall provide evidence of its commitment to the development and implementation of the management system and its effectiveness in achieving consistent fulfilment of the requirements of this document.

8.3 Documented information

8.3.1 The inspection body shall control the documents (internal and external) that relate to the fulfilment of the requirements of this document. The procedures for the control of documents shall ensure that:

a) documents are approved for adequacy prior to issue by authorized personnel;

b) documents are periodically reviewed and updated as necessary;

c) changes and current revision status of documents are identified;

d) relevant versions of applicable documents are available at points of use and their distribution is controlled;

e) documents are uniquely identified;

f) documents of external origin are identified and their distribution controlled;

g) the unintended use of obsolete documents is prevented and that suitable identification is applied to them if they are retained for any purpose.

NOTE Documentation can be in any form or type of medium, and includes proprietary and in-house developed software.

8.3.2 The inspection body shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retaining and disposal of its records.

8.3.3 The inspection body shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments and records shall be readily available.

NOTE Additional requirements regarding inspection records are given in 7.4.

8.3.4 All documentation, processes, systems and records related to the fulfilment of the requirements of this document shall be included in, or referenced from, the management system.

8.3.5 All personnel involved in inspection activities shall have access to the documented information that is applicable to their responsibilities.

8.4 Actions to address risks and opportunities

8.4.1 The inspection body shall consider the risks and opportunities associated with the inspection activities to:

a) give assurance that the management system achieves its intended results;

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b) enhance desirable effects to achieve the purpose and objectives of the inspection body;

c) prevent or reduce undesired impacts and potential failures in the inspection body;

d) achieve improvement.

8.4.2 The inspection body shall plan:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement these actions into its management system;

2) evaluate the effectiveness of these actions.

NOTE Although this document requires that the inspection body take actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. The inspection body can decide whether or not to develop a more extensive risk management methodology, e.g. through the application of other guidance or standards.

8.4.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of the inspection results and, if relevant, on the validity of the inspection scheme.

NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to expanding the scope of the inspection activities, addressing new clients, using new technology and other possibilities to address client needs.

NOTE 3 Some techniques to ensure validity of inspection results can be:

— reinspect items;

— compare results from different inspectors on the same item;

— analyse trends from individual inspectors;

— comparison with results of other inspection bodies;

— onsite monitoring;

— review of reports.

8.4.4 The inspection body shall seek feedback from its clients and, if relevant, its interested parties. The feedback shall be analysed and used to improve the management system and inspection activities.

NOTE Examples of the types of feedback include clients and, if relevant, its interested parties satisfaction surveys, communication records, the use of existing mechanism for feedback and review of reports with personnel, interested parties or clients.

8.5 Corrective actions

8.5.1 The inspection body shall have a procedure for identification and management of nonconformities. This shall include any aspect of the management system and operations that do not conform to the inspection body’s own procedures or this document, as well as inspection activities that do not conform to inspection body's procedures or agreed requirements of the client.

8.5.2 When a nonconformity occurs, the inspection body shall:

a) ensure that the responsibilities and authorities for the management of nonconformities are defined;

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b) react to the nonconformity and, as applicable:

   1) take action to control and correct it;

   2) address the consequences;

c) evaluate the need for action to eliminate the cause(s) of any nonconformity, in order that it does not recur or occur elsewhere, by:

   1) reviewing and analysing the nonconformity;

   2) determining the causes of the nonconformity;

   3) determining if similar nonconformities exist, or can potentially occur;

d) implement any action needed, in a timely manner;

e) review the effectiveness of any corrective action taken;

f) update risks and opportunities determined during planning, if necessary; and

g) make changes to the management system, if necessary.

8.5.3 In the case of nonconformities related to inspection activities that do not conform to the inspection body's own procedures or the requirements agreed with the client, the inspection body shall, in addition to 8.5.2 c) to g), also ensure that:

— actions that are defined (including halting or repeating of work and withholding of reports, as necessary), are based upon the risk established by the inspection body;

— an evaluation is made of the significance of the nonconformity, including an impact analysis on previous results;

— a decision is taken on the acceptability of the inspection work affected by the nonconformity;

— where necessary, the client is notified and work is recalled or disregarded;

— the responsibility for authorizing the resumption of work is defined.

8.5.4 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.5.5 The inspection body shall retain records of:

a) the nature of the nonconformities, causes and any subsequent actions taken (8.5.2 to 8.5.4);

b) the effectiveness of any corrective action.

8.6 Internal audits

8.6.1 The inspection body shall conduct internal audits at planned intervals to provide information on whether it:

a) conforms to:

   1) the inspection body’s own requirements for its management system, including the inspection activities;

   2) the requirements of this document;

b) has effectively implemented and maintained the required management system.

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8.6.2 The inspection body shall:

a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the inspection activities concerned, changes affecting the inspection body and the results of previous audits;

b) ensure that internal audits are performed by personnel knowledgeable in conducting inspection activities and auditing and the requirements of this document and that these personnel do not audit their own work;

c) define the audit criteria and scope for each audit ensuring that all requirements of this document are covered by the internal audit programme; the requirements to be covered shall be considered for all fields of inspection and for all premises where inspection activities are managed or performed;

d) ensure that the results of the audits are reported to relevant management and to the personnel responsible for the area audited;

e) implement appropriate corrections and corrective actions without undue delay;

f) identify any opportunities for improvement;

g) retain records as evidence of the implementation of the audit programme and the audit results.

8.7 Management review

8.7.1 The inspection body management shall review its management system at planned intervals in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of the requirements of this document.

8.7.2 The inputs to the management review shall be recorded and shall include information related to the following:

a) internal and external changes that are relevant to the inspection body;

b) suitability of policies and procedures;

c) outcome of recent internal audits;

d) assessments by external bodies;

e) client, personnel, and, if relevant, interested parties feedback;

f) corrective actions;

g) status of actions from previous management reviews;

h) the fulfilment of objectives;

i) changes in the volume and type of the work or in the range of inspection activities;

j) appeals and complaints;

k) effectiveness of any implemented improvements;

l) adequacy of resources including current human and equipment resources, projected workloads and the need for training of both new and existing personnel;

m) results of risk identification including impartiality threat identification process and its conclusions;

n) review of the effectiveness of processes established to ensure adequate competence of the personnel, including monitoring and training of inspectors and other personnel involved in inspection activities;

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o) other relevant factors.

8.7.3 The outputs from the management review shall record all decisions and actions related to:

a) the effectiveness of the management system and its processes;

b) improvement of the activities related to the fulfilment of the requirements of this document;

c) provision of required resources;

d) any need for changes.

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Annex A
(normative)

Independence requirements for inspection bodies

A.1 Requirements for type A inspection bodies

A type A inspection body shall meet the requirements below.

a) The inspection body shall be independent of the parties involved.

NOTE 1 The parties involved can include, but are not limited to, the client, either the owner or the user, or both, of the item inspected, or the organization involved in the design, manufacture, supply, installation, or maintenance of the items. The parties involved also include potential purchasers of the item inspected, and possibly a relevant regulatory authority or other statutory authority.

NOTE 2 While the results of an inspection can have implications for the public, the public is not considered to be a "party involved".

b) The inspection body and its personnel shall not engage in any activities that can conflict with their independence of judgment and integrity in relation to their inspection activities. In particular, they shall not be engaged in the design, manufacture, supply, installation, purchase, ownership, use, maintenance of the item inspected, or similar competitive items.

NOTE 3 This does not preclude exchanging technical information between the client and the inspection body (e.g. explanation of findings or clarifying requirements or training).

NOTE 4 This does not preclude the purchase, ownership or use of inspected items that are necessary for the operations of the inspection body, or the purchase, ownership or use of the items for personal purposes by the personnel.

NOTE 5 "Similar competitive" means an item that is an alternative (in terms of price, quality and other technical specifications) to the item inspected and competing in the market.

c) The inspection body shall not be a part of a legal entity that is engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the item inspected or similar competitive items.

NOTE 6 This does not preclude exchanging technical information between the client and any other part of the same legal entity of which the inspection body is a part (e.g. explanation of findings or clarifying requirements or training).

NOTE 7 This does not preclude the purchase, ownership, maintenance or use of inspected items that are necessary for the operations of another part of the same legal entity, or for personal purposes by the personnel.

d) The inspection body shall not be linked to a separate legal entity engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the item inspected or similar competitive items by the following:

1) common ownership, except where the owners have no ability to influence the outcome of an inspection;

EXAMPLE 1 A cooperative type of structure where there are large numbers of stakeholders, but they (individually or as a group) have no ability to influence the outcome of an inspection.

EXAMPLE 2 A holding company consisting of several separate legal entities (sister companies) under a common mother company, where neither the sister companies nor the mother company can influence the outcome of an inspection.

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2) common ownership appointees on the boards or equivalent of the organizations, except where these have functions that have no influence on the outcome of an inspection;

EXAMPLE 3 A bank financing a company insists on an appointee to the board who will overview how the company is managed but will not be involved in any decision-making.

3) directly reporting to the same higher level of management, except where this cannot influence the outcome of an inspection; reporting to the same higher level of management is permitted on matters other than the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the item inspected or similar competitive items;

4) any means that can establish the ability of the separate legal entity to influence the outcome of an inspection, including but not limited to contractual commitments that establish the separate legal entity's control or authority over the inspection body.

A.2 Requirements for type non-A inspection bodies

An inspection body that does not meet the requirements of Clause A.1 shall meet the requirements below.

a) The legal entity, (see 5.2.1), shall provide safeguards within the organization to ensure adequate segregation of responsibilities and accountabilities between inspection and other activities.

b) The design, manufacture, supply, installation, servicing, maintenance and the inspection of the same item performed by the inspection body shall not be undertaken by the same person. An exception to this is where a scheme requirement explicitly allows an individual person from an inspection body to undertake both the design, manufacture, supply, installation, servicing, maintenance and the inspection of the same item, as long as this exception does not compromise the inspection results.

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Annex B
(informative)

Optional elements of inspection reports and certificates

The following optional elements are examples and can be included in inspection reports and certificates:

a) designation of the document, i.e. as an inspection report or an inspection certificate, as appropriate;

b) identification of the client;

NOTE The owner of the item inspected can be mentioned in the report or certificate if the owner is not the client.

c) description of the inspection work ordered;

d) information on what has been omitted from the original scope of work;

e) identification or brief description of the inspection method(s) and procedure(s) used, mentioning the deviations from, additions to or exclusions from the agreed methods and procedures;

f) identification of equipment with significant influence;

g) where applicable, and if not specified in the inspection method or procedure, reference to or description of the sampling method and information on where, when, how and by whom the samples were taken;

h) information on environmental conditions during the inspection, if relevant;

i) a statement that the inspection results relate exclusively to the work ordered or the item inspected;

j) a statement that the inspection report should not be reproduced, except in full;

k) the inspector's mark or seal, secure electronic authentication or their signature.

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